Implementation Support Document
ISD 840-1.0

Procurement Quality

Los Alamos National Laboratory

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Issued by: Richard A. Marquez

Contact: Institutional Quality Management (PS-1), 665-5437

REVISION HISTORY

Revision No.	Description of Change	Issue Date
0	New Document	01/03/06

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1.0 INTRODUCTION

1.1 Authority

This Implementation Support Document (ISD) is issued under the authority of the Associate Director of Administration (ADA). This ISD supports IP 300-SD3, *LANL Quality Assurance Program* (QAP), and complies with the requirements contained therein. The Institutional Quality Management Group (PS-1) of the Performance Surety Division is the Responsible Office (RO) for this ISD. Training responsibility for this ISD will reside with the Issuing Authority (ADA).

1.2 Applicability

This ISD applies to all LANL organizations and employees (see **Exceptions** below), including subcontractors, responsible for and involved in the process of procuring Management Level (ML) -1 and ML-2 items, materials, and/or services at LANL within the contractual agreements of the prime contract.

This ISD applies to ML-3 and ML-4 items and services only as noted below:

- Items/commodities prone to be suspect/counterfeit must be receipt inspected (see Section 4.4.4)
- Items and services that must be procured via a purchase request (see Section 4.4.4).

Guidance for LANL procurement of ML-3 and 4 items, materials and services is provided in ISD 840-2, *Requester Guide for Meeting Requirements for Procurement of Items and Services*.

Exceptions:

[1] This ISD does not apply to the weapons manufacturing program as established by the weapons engineering and manufacturing administrative procedures (WEM-AP).

[2] This ISD does not apply to the process for obtaining items or services from other DOE sites/management companies, other campuses of the University of California, and between LANL divisions/organizations. This process is covered by the following University of California Procurement Standard Practices procedures:

- 8.2, Government Sources General
- 8.4, *Orders with DOE M&O Contractors*
- 8.5, *Orders Against GSA Federal Supply Schedule*
- 44.1, *Intra-University Transactions*

This ISD rescinds LIR 308-00-04 Procurement actions initiated prior to the issue date of this ISD will comply with LIR 308-00-04.

This ISD goes into effect upon the issue date and its implementation will be phased according to the schedule in Attachment 7.

1.3 Purpose

This ISD integrates Quality Assurance (QA) controls into the procurement process for ML-1 and ML-2 items and services at LANL by defining the requirements and responsibilities to ensure that:

- Technical and quality requirements for items and services to be procured are adequately specified in procurement documents;
- Prospective suppliers (and distributors, as applicable) are evaluated and selected on the basis of specified criteria;
- Procured items and services meet established requirements and perform as specified; and
- Processes are established and implemented to ensure that approved suppliers/distributors continue to provide acceptable items and services.

1.4 Change Control

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The formal process required for revising, reviewing and approving changes to this ISD will be administered by the Performance Surety (PS) Division. As specified in ISD 311-1, *Manual for Preparing Policies, Procedures and Related Documents*, the Policy Office (POL) has the authority to make corrections or minor revisions to any LANL policy or procedure at any time if required, and will do so for this ISD. However, if the revision to this ISD requires substantial change to any of the procedures in this ISD, PS will send out a draft of the revised ISD for review and comment for a specified number of working days. PS will address the comments and, when they have been resolved provide to the POL:

- The revised document (hard copy and electronic file in MS Word),
- Written evidence that the IA has approved the revision, the issue date of the revision, and
- A synopsis of the change.

2.0 DEFINITIONS AND ACRONYMS

2.1 Definitions

Approved Supplier (also referred to as "Qualified Supplier"): A supplier whose management and operations have been evaluated in accordance with approved procedures and found to be capable of assuring the specified quality of items or services being requested in a procurement document.

Calibration: The set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards.

Certificate of Conformance: A document signed or otherwise authenticated by an authorized individual certifying the degree to which items or services meet specified requirements.

Commercial Grade Item: Any item satisfying the following:

- Not subject to design or specification requirements that are unique to the nuclear facilities
- Routinely used in applications other than nuclear facilities
- To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog)

Commercial Grade Survey: Activities conducted by LANL or its agent to verify that a supplier of commercial grade items controls, through quality activities, the critical characteristics of the specifically designated commercial grade items. It is used as a method to accept commercial grade items for ML-1, ML-2, and Vital Safety Systems (VSS) end uses.

Conditionally Approved Supplier: A supplier whose quality and management systems have been evaluated in accordance with the requirements of this ISD and determined not to have the required capabilities without certain limitations or restrictions for providing items or services in accordance with established requirements.

Conformance Documentation: Authenticated (signed, stamped, or initialed and dated by authorized personnel) records of observed characteristics that confirm the conformance of items or services to specifications; e.g., an acceptance report based on receipt inspection and/or testing.

Corrective Action: Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.

Corrective Action Report (or Request): A written report that identifies one or more conditions adverse to quality requirements, corrective action, cause determination, and when required, preventive actions for re-currence.

Critical Characteristics: a) Those properties or attributes which are essential for the item's form, fit, and functional performance. Critical characteristics are the identifiable and/or measurable attributes of an item that provide assurance that the item will perform its intended design function. b) Those important design, material and performance characteristics (form, fit and function) of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Dedication: An acceptance process performed in accordance with approved procedures to provide reasonable assurance that a commercial grade item will successfully perform its intended safety function and, in this respect, is deemed equivalent to an item provided under the requirements of this ISD.

Deficiency: Any condition of noncompliance to planned contract requirements identified during a qualification audit or during the acceptance of services.

Deviation: A departure from specified requirements.

Graded Approach: The process of ensuring that the level of analyses, documentation, and actions used to comply with requirements are commensurate with:

- The relative importance to safety, safeguards, and security;
- The magnitude of any hazard involved;
- The life-cycle stage of a facility;

- The programmatic mission of a facility;
- The particular characteristics of a facility;
- Any other relevant factors.

Inspection: Examination or measurement to verify whether an item or activity conforms to specified requirements.

Institutional Evaluated Suppliers List (IESL): A list indicating acceptability of suppliers whose quality management systems have been evaluated for their capability to supply items or services in accordance with established requirements. The IESL is maintained by PS-1.

Item: An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

Management Levels: The LANL classification system for determining that the management control applied to each facility/project element or deliverable is consistent with its intended performance, complexity, governing codes, standards or regulatory requirements, mission, importance, environmental consequence, and safety and health risks.

Material Test Report (also known as Certificate of Analysis): A certificate issued by the original fabricator of the material, part, or equipment which is traceable to the shipment through a unique identification number and which indicates measured chemical and physical properties as specified in the applicable procurement document and that the test(s) was performed in accordance with applicable nationally recognized standards.

Measuring and Test Equipment (M&TE): Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

National Institute of Standards and Technology (NIST): The highest-level metrology organization in the United States. NIST serves as the source of traceability for most measurements in this country.

Nonconformance: A deficiency in characteristics, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Procurement: The LANL process to obtain items or services through purchase orders, subcontracts, or other procurement documents or mechanisms.

Procurement Document: Purchase requests, statement/scope of work, purchase orders, drawings, contracts, specifications or instructions used to define requirements for purchase.

Purchase Request: The document that sets forth procurement requirements for items and services, and authorizes purchasing actions by SUP Division.

Qualification Audit: Performed to verify that a supplier is capable of meeting the requirements of a planned LANL purchase order.

Qualification (personnel): The characteristics or abilities gained through education, training, or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function.

Quality: The degree to which an item or process meets or exceeds the user's requirements and expectations.

Quality Assurance (QA): All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality Subject Matter Expert: The person (e.g., American Society for Quality [ASQ] Quality Engineer or Quality Manager, LANL Quality Assurance Engineer, LANL Quality Assurance Specialist, etc.) designated responsibility for quality assurance support to a facility, project, group, or other organizational unit who has demonstrated competence and expertise in the interpretation and application of DOE and national quality assurance consensus standards for nuclear facilities.

Receiving Inspection: A post delivery, independent inspection performed as part of the acceptance process to verify that ordering requirements have been met.

Repair: The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safety is unimpaired, even though that item still does not conform to the original requirement.

Rework: The process by which an item is made to conform to original requirements by completion or correction.

Risk: A function of the likelihood and potential severity of injury, harm, incurred liability, damage or loss; a qualitative judgment based on knowledge and experience.

Service: The performance of activities such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Shelf Life: The length of time an age-sensitive material can be stored under prescribed conditions and still confidently retain its properties such that it will function as intended when put into service. The most common shelf life items are: gaskets, o-rings, seals, v-belts, and hoses made of elastomeric materials; and many paints, sealants, adhesives and chemicals.

Source Inspection: Planned and documented inspections performed by qualified inspection personnel, designated by management, at the manufacturer's or supplier's location, usually during the manufacturing or procurement process and prior to shipment.

Supplier: Any individual or organization that furnishes items or services in accordance with a procurement document. An all-inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their sub-tier levels.

Supplier Deviation: A departure from the procurement requirements identified prior to products or services being furnished to LANL for acceptance.

SUP Procurement: The LANL Supply Chain Management (SUP) Division Procurement Group and its delegated individuals authorized to execute purchase orders and subcontracts.

Suspect/Counterfeit Item (S/CI): A suspect item is one in which visual inspection, testing, or other means indicates that it may not conform to established Government or industry-accepted specifications or national consensus standards; or one who's documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer. A counterfeit item is a suspect item that has been copied or substituted without legal right or authority to do so, or whose material, performance, or characteristics are misrepresented by the supplier or manufacturer.

Technical Justification: A statement defining the basis for the proposed course of action. This basis must be founded on statements of fact derived from calculations, evaluations, codes, standards, documented history, or other technical sources. Sufficient detail must exist to allow a peer subject matter expert to confirm the validity of the statement.

Technical Requirement: The characteristics, performance capabilities, etc., which define the critical characteristics (the necessary and sufficient salient features of an item) to ensure that the item will meet functional requirements. Technical requirements for services describe the conditions for the service or product to be provided.

Technical Subject Matter Expert: The person (e.g., Responsible Engineer, System Engineer, Process Engineer, Principle Investigator, Scientist, etc.) who has demonstrated competence and expertise in a specific process, service, or item and is authorized to determine technical or performance adequacy, specifications, codes, standards, and/or quality-related requirements; or other personnel designated by management (Team Leader or above).

Testing (also referred to as Acceptance Testing): An element of verification for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Traceability: The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-as-is: A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification: The act of reviewing, inspecting, testing, checking, auditing, or otherwise establishing and documenting whether items, processes, services, or documents conform to specified requirements. In this document, verification refers to a calibration performed by the using organization.

Vital Safety System: A system meeting one of the following criteria: Active safety class and safety significant structures, systems, and components as defined in the nuclear facility's DOE-approved safety basis; or other active systems that perform an important defense-in-depth function for the protection of the public, workers, or the environment within the context of the safety basis, as designated by the facility line management.

2.2 Acronyms

FESS — Facility Engineering Standards and Services

IESL — Institutional Evaluated Suppliers List

ML — Management Level

M&TE — Measuring and Test Equipment

NIST — National Institute of Standards and Technology

SOW — Statement of Work

UTR —University Technical Representative

3.0 RESPONSIBILITIES

3.1 RLM

- Completing the training required by this ISD.
- Ensuring that the requirements contained in this ISD are implemented with the rigor, depth, and detail to provide confidence that procured items and services will not adversely impact the: health and safety of the public and LANL personnel, environment, mission, and/or security and safeguards.
- Ensuring qualified and authorized personnel determine technical and performance specifications, perform acceptance and test procedures, perform inspections, and validate expected item and service functionality.
- Ensuring items are inspected and accepted per defined criteria by qualified and authorized personnel.
- Ensuring that those responsible for the determination of the ML of items or services are adequately qualified technical personnel.
- Ensuring the assignment of Technical and Quality SME to fulfill the responsibilities of this ISD.

3.2 Requesters

- Completing the training required by this ISD.
- Preparing procurement documents in accordance with this ISD.
- Determining ML of items or services and recording the ML on the purchase request and/or other applicable procurement documents.
- Coordinating with SUP Procurement.
- Recommending qualified candidate suppliers or assuring commercial grade item dedication is specified.
- Preparing procurement specifications, statements of work, and inspection/acceptance criteria.
- Providing personnel to function as Technical SME & Quality SME to ensure the adequacy of technical and quality requirements invoked in procurement documents provided to SUP.
- Providing technical support to supplier evaluations and assessments as required by QA requirements.
- Verifying that items and services have been accepted in accordance with this procedure prior to use or installation of the item or use of the service data/deliverables.
- Ensuring supplier submittals required by the Purchase Order are submitted and are satisfactory.
- Conducting receipt inspections per this ISD, at their discretion.

3.3 Technical Subject Matter Expert (TSME)

- Completing the training required by this ISD.
- Determining ML and identifying technical and quality requirements of items/services to be procured.
- Ensuring correct reference to technical documents, such as the Engineering Standards Manual, and other required specifications and standards, are incorporated into procurement requests and specifications.
- Determining, in conjunction with Quality SME, if quality requirements should be invoked for ML-3 and ML-4 items and services.
- Developing or assisting in the development of procurement specifications and Statements of Work (SOW).
- Assisting in the resolution of supplier deviations and nonconformances, including development of dispositions and corrective actions.

3.4 Quality Subject Matter Expert (QSME)

- Completing the training required by this ISD.
- Confirming that procurement request documentation identifies the applicable ML appropriate to end use of the items/services to be procured.
- Ensuring appropriate QA requirements are invoked for ML-1 and ML-2 procurement actions.
- Determining, in conjunction with the TSME, if quality requirements should be invoked for ML-3 and ML-4 item/services.
- Consulting with requesters to resolve any questions resulting from procurement document reviews.
- Performing supplier evaluations and source verifications (in conjunction with TSME, as appropriate).

3.5 SUP Procurement Specialist

- Completing the training required by this ISD.
- Assuring that specified documents are included and/or referenced in purchase orders/contracts.
- Ensuring procurement documents for ML-1 and ML-2 items and services include the Supplier Quality Clauses indicated on Form 838c.
- Preparing solicitation packages and sending them to prospective offerors.
- Coordinating supplier exceptions/clarifications to the solicitation package.
- Ensuring award to appropriately qualified suppliers.
- Formally appointing a UTR via a Letter of Delegation.
- Communicating with suppliers on performance issues.

3.6 University Technical Representative (UTR)

When assigned via a Letter of Delegation (reference LANL – Supplemental Instruction 42.5, University Technical Representatives) perform specified technical or administrative oversight duties for a specific subcontract including:

- Initiating performance improvements with suppliers.
- Initiating non-conformance reports to report supplier non-conformances and/or processing non-conformance reports initiated by the supplier in accordance with the requirements of the applicable procedures for the control of nonconformances and/or corrective action.
- Approving "Scrap" dispositions for nonconforming LANL-supplied materials.
- Approving technical justifications provided by suppliers to support "Use-as-is" or "Repair" dispositions for nonconforming items.

3.7 SUP 3 Materials Management

- Providing receiving, storage, control, and delivery of procured items in accordance with the requester organization documented requirements.

3.8 PS-1 Institutional Quality Management

- Developing and maintaining this ISD, Form 838c, and ISD 840-2, *Requester Guide for Meeting Requirements for Procurement of Items and Services*.
- Upon request, assisting in development of quality assurance criteria, specifications and inspection/test plans.
- Upon request, reviewing and approving procurement documents to ensure that required technical and quality requirements are specified and appropriate.
- Assisting LANL organizations in identifying and selecting approved suppliers from the Institutional Evaluated Suppliers List (IESL).
- Upon request, supporting requesters and other divisions, programs, and projects with supplier assessments.

3.9 PS-1 Quality Assessment Team

- Establishing and maintaining the institutional supplier evaluation system for on-site or desktop supplier evaluations.
- Performing evaluations and source inspections to qualify suppliers/distributors for inclusion on the IESL.
- Maintaining records of supplier evaluation, assessment, and source inspection results.

3.10 PS-1 Receipt Inspection Team

- Provide training and certification to LANL receipt inspection personnel.
- Perform and document inspections and tests required by procurement documents.
- Ensure that test/inspection and supplier transmitted documentation is maintained with the material during the test/inspection and subsequently transmitted to the requester with the accepted items.

3.11 Engineering

- Completing the training required by this ISD.
- Upon request, determining the ML and identifying technical requirements of items/services to be procured.
- Upon request, supporting requesters in developing procurement specifications or SOW.
- Upon request, providing LANL developed and documented programmatic standard specifications (e.g., glove box specifications).
- Reviewing and approving applicable ML-1 and ML-2 procurement documents, (e.g., purchase requests, procurement specifications, SOWs, Form 838c).
- Approving exceptions/clarifications to technical aspects of procurement documents for ML-1 and ML-2 items and services, as appropriate.
- Reviewing and approving engineering documents submitted by suppliers, when required.
- Maintaining the Engineering Standards Manual, construction specifications/standards, and drafting standards.

4.0 INSTRUCTIONS

4.1 General

The LANL procurement process incorporates a graded approach for managing procurement actions at a level of rigor commensurate with the functional, quality, and technical requirements associated with the intended use or application of the procured item or service. The grading of items and services is based on the designated ML (Section 4.2).

Procurement of items or services for applications with greater levels of risk (ML-1 and ML-2) requires QA controls on a graded basis (successively more for ML-1 than for ML-2 items and services). The procurement of ML-1 and ML-2 items and services must be initiated via a purchase request. All purchase requests must be reviewed and approved by the responsible TSME and QSME.

Procurement of items and services with lower levels of risk (ML-3 and ML-4) do not require the application of QA controls. If deemed necessary, a Technical SME or Project/Facility Management may opt to apply QA controls to the procurement of ML-3 and ML-4 items and services.

The graded approach embodies the principles contained in the Integrated Safety Management (ISM) system established at LANL and ensures a systematic approach to identifying and mitigating hazards and risks at LANL.

4.2 Determining and Documenting Management Levels

[1] Items and services that meet the following criteria will be deemed ML-4, do not require documentation of ML on any procurement documentation, and should be procured in accordance with the guidance provided in ISD 840-2, *Requester Guide for Meeting Requirements for Procurement of Items and Services*:

> Management Level 4 Items and Services: Recognized as having no risk (e.g. basic office supplies, basic shop tools, etc.), thus no actual or potential risk to the health and safety of site personnel or the public; the environment; or to LANL mission or security.

[2] For items or services to be procured that **DO NOT** meet the ML-4 criteria provided in Section 4.2.1, the requester, in conjunction with the TSME (if the requester is not the TSME), determines if the ML has already been designated and documented. **IF YES, THEN** proceed to Section 4.2.5.

[3] **IF** the items/services to be procured have **NOT** previously been designated and documented a ML or the designated ML is suspected as erroneous, **THEN** the TSME will determine the applicable ML in accordance with Section 4.2.4.

[4] TSME determines the management level of structures, systems, and components (SSC) in accordance with the current revision of:

LIR 230-01-02, Graded Approach for Facility Work
AP-341-502, *Management Level Determination for Structures, Systems, and Components* (no link available)

NOTE: Technical SME performing ML determinations may be Requesting Organization personnel or personnel from other LANL organizations.

[5] **IF** the ML has been established and documented as ML-1 or ML-2 or determined to be ML-1 or ML-2 per Section 4.2.4, **THEN** the requester records the ML on Form 838c and on the Purchase Request found on the Procurement Home Page.

NOTE: All 838c forms must be reviewed and approved by the responsible Technical and Quality SMEs.

NOTE: With the exception of items prone to be deemed suspect/counterfeit (see Section 4.4.4), items and services determined to be either ML-3 or ML-4 do not require completion of a Form 838c and may be procured via the most appropriate procurement method.

4.3 Identification of Functional Requirements

[1] The TSME determines the functional requirements needed to be satisfied by the deliverable (ML-1 and ML-2 items or services). Functions would include such considerations as containment, fire prevention requirements, space requirements, flow control, consulting, training, or spare parts. The functional requirements provide the basis upon which technical requirements are identified.

[A] Functional requirements include a general description of the end result that is desired. Examples include: achieve shutoff of water flow through a pipe (valve); or stop fluid flow within 30 seconds of an alarm sounding (valve), maintain ventilation at sub-atmospheric pressure (fan), or at a negative pressure with relation to the office area (fan).

[B] Examples of functional requirements for services could include: evaluate the adequacy of the building structure to withstand an 80-mph tornado (engineering study); provide HAZMAT training for 100 employees; or provide services to maintain roads and bridges at LANL.

[2] The TSME identifies the conditions under which the functional requirements must perform. These conditions can be dependent upon such factors as time, duration of the function, or an external triggering event. Identified conditions may contribute to or impact technical requirements that will be established.

[3] The TSME identifies whether the deliverable is an item, a service, or a combination of items and services. This determination will focus the procurement process and assist in the identification of applicable technical and quality requirements.

4.4 Specification of Performance and Technical Requirements

Performance and technical requirements for ML-1 and ML-2 items and services will be specified by the responsible TSME in Procurement Specifications (Section 4.5), Statements of Work (Section 4.6), and/or Task Orders (Section 4.7).

[1] Performance Requirements

The TSME determines the performance requirements needed to be satisfied by the item or service. (See Attachment 1 for additional information/guidance.)

[2] Salient Features and Critical Characteristics

The TSME identifies the necessary and sufficient salient features of the deliverables that are required to meet the functional requirements. The necessary and sufficient salient features are a subset of the salient features, and are described as the “critical characteristics” for the purposes of this ISD.
(See Attachment 5 for additional information/guidance.)

[3] Management Level

The TSME identifies the ML of facility-based items per Section 4.2.

[4] Other LANL Requirements

The TSME ensures that applicable requirements in other LANL procedures/documents, (e.g., Engineering Standards Manual, Chapter 10, “Hazardous Process” or Chapter 11, “Radiation Protection”) are identified and addressed. The TSME consults with SME in these areas as necessary.

For procurements (items or services) that require subcontractors to perform work at LANL, the TSME complies with LIR 402-10-03, *ES&H Management of Contractor Performed Facility Construction/Maintenance, Environmental Restoration/Decontamination and Decommissioning, and Related Drilling Operations*.

Additional requirements regarding controls for the acquisition of software are found in LIR 308-00-05, *Software Quality Management*.

The procurement of certain items or services are required to be reviewed and approved by designated LANL SMEs to ensure that safety, security, quality assurance, and other requirements of the LANL Prime Contract are adhered to. The list of items and services requiring review and approval are contained in LANL Procurement Standard Practices 4.10, Internal Reviews and Approval, Form 410. Procurement of the items and services on Form 410 will be initiated via a purchase request, regardless of designated management level. To expedite the procurement process, obtain these reviews and approvals prior to submitting purchase requests to the applicable Procurement Specialist.

In addition to the item/services listed on Form 410, procurement of the following items and services will be initiated via a purchase request, regardless of designated ML:

- Cranes;
- Lightning protection equipment and components;
- Life safety equipment (personal protective equipment such as safety harnesses, self-contained breathing apparatus, and particulate, chemical, or gas mask, dielectric gloves, etc.);
- Pressure vessels;
- Pressure and safety relief valves for cryogenic systems and systems that exceed 150 psi;
- Containers, drums, packaging systems or component parts to be used for transporting hazardous materials, substances, or waste;
- Radiation barrier material (lead glass, lead panels, etc);
- High efficiency particulate air (HEPA) filters (contact LANL HSR Division);
- Calibration services;

The following items/commodities have a history of being counterfeited thus must be receipt inspected to prevent suspect/counterfeit items from being introduced into the Laboratory. In order to ensure that these items/commodities are receipt inspected, the TSME must initiate the procurement via a purchase request and complete a Form 838c, regardless of designated ML. At a minimum, Quality Clause 26, *Suspect/Counterfeit Items* must be indicated on Form 838c.

- Threaded fasteners, including assemblies containing fasteners such as ratchet tie down straps;
- Electrical components (circuit breakers, semi-conductors, current and potential transformers, fuses, resistors, switchgear, overload and protective relays, motor control centers, heaters, motor generator sets, DC power supplies, AC inverters, transmitters, GFCI)
- Piping components (fittings, flanges, valves and valve replacement parts, couplings, plugs, spacers, nozzles, pipe supports);
- Preformed metal structures, semiconductors, elastomers (O-rings, seals), spare or replacement kits from suppliers other than original equipment manufacturers, weld filler material, diesel generator speed governors and pumps;
- Material, including sheet strip, castings and other forms particularly involving those materials for which special processes are required (i.e., welding, heat treating) for conformance to specifications.

  NOTE: A current list of specific items/commodities prone to be suspect/counterfeit is available on the PS-1 Home Page. Also, see ISD 330-9, *Suspect/Counterfeit Items* for additional information.

[5] Replacement Item Evaluation/Commercial Grade Item Dedication

The TSME determines if the item is a Commercial Grade Item (CGI) that will be used in a Safety Class (SC) or Safety Significant (SS) application. For CGI, the TSME performs replacement item evaluation or commercial grade item dedication in accordance with ISD 330-10, *Commercial Grade Item Dedication*. This process identifies critical characteristics as appropriate.

The TSME determines if the CGI is suitable for use without performing dedication per AP-341-503, *Engineered Equivalent Determination*.

[6] Identification of Acceptance Criteria

The TSME identifies, as applicable, criteria that will be used to determine that the supplier's deliverable is acceptable. This may involve inspections, tests and test results, and review of documents.

NOTE: With the exception of post-delivery/post-installation testing (see Attachment 2, page 3), ML-1 and ML-2 items may not be used for their specified/intended end use without receipt inspection documentation indicating satisfactory results.

Refer to Attachment 2 for information/guidance regarding the identification of acceptance criteria.

[7] Packaging, Handling, Shipping, and Storage Requirements

The TSME identifies any specific packaging, handling, shipping requirements per guidance provided in Attachment 3. The TSME may conclude that the supplier's standard meets the identified requirements. If so, simply state that Supplier Standard shall be met. The TSME may also specify supplier standard and include specific packaging, shipping and handling requirements to ensure adequate protection.

Additional requirements regarding hazardous and radioactive materials are found in the Engineering Standards Manual, Chapters 10 and 11 respectively.

For LANL storage requirements, the TSME determines the storage level in accordance with Attachment 6.

In determining the packaging, handling, shipping, and storage requirements to be included in procurement requirement documents, the TSME:

[A] Should evaluate whether a supplier's packaging, handling and shipping standard will meet LANL requirements; a submittal from the supplier may be desirable for this evaluation. LANL acceptance could be based simply on undamaged receipt.

[B] To supplement the supplier's standard, may need to identify specific packaging, handling, and shipping requirements for the storage level selected (see Attachment 6). The amount of detail provided to the supplier should be commensurate with the complexity and sensitivity of the item(s) to be supplied.

NOTE: Storage requirements are generally not specified unless the supplier needs to store the item.

[8] Marking and Identification Requirements

The TSME identifies any specific marking and identification requirements for the item(s) being procured. See additional information in Attachment 4.

The need for marking and identification is determined based on the following:
- Operational requirements
- Codes and standards used
- Complexity/criticality of the item
- End use and the consequence of failure of the item
- Traceability requirements
- Functional classification
- Shipping, Receiving, and Storage requirements

[9] Shelf Life

The TSME determines shelf life requirements for items suspected of having shelf life requirements. The most common shelf life items are: gaskets, o-rings, seals, v-belts, and hoses made of elastomeric materials; and many paints, sealants, adhesives and chemicals.

For materials where a manufacturer/cure date and shelf life or expiration date are commonly labeled on the part or material (e.g., coatings, paints, chemicals, medicines), specify that a manufacture/cure date and expiration date must be provided for the items.

For items that normally have an expiration date marked on the package by the manufacturer, but no manufacture/cure date (e.g., batteries, film), specify that the expiration date is to be labeled on the package by the manufacturer.

Specify that the supplier provide documentation indicating the manufacture or cure date or a date-coded package for the item/materials that have a shelf life which is not commonly labeled on the part or material (e.g., elastomers).

The manufacturer should be contacted for shelf life recommendations.

4.5 Procurement Specifications

Procurement specifications document clear and accurate descriptions of:

- performance and technical requirements;
- deliverables;
- quality requirements;
- responsibilities;
- packaging, handling, and storage requirements;
- applicable codes, standards and drawings; and
- acceptance / rejection criteria (Section 4.4.6) for items or services.

Responsible line management designates a TSME and QSME for each procurement specification. The TSME is the primary point-of-contact for any issues with the technical requirements of the specification and procurement and the QSME serves as the point of contact for any issues with the quality requirements of the specification and procurement. Point of contact may entail interaction between Procurement Specialists, requesters, suppliers, etc.

At a minimum, procurement specifications will be reviewed and approved by a responsible TSME and a QSME.

NOTE: A number of standard specifications for engineered systems and components are available through the LANL Construction Specifications Manual found at Engineering Standards Home Page. The standard procurement specifications should be used whenever possible to facilitate the minimization of costs for the procurement action. Engineering administers a process to establish and maintain standard specifications, and can provide systems engineering support for developing procurement specifications.

4.6 Statements of Work

SOW must include desired objectives, detailed descriptions of items or services being procured, key responsibilities, reference to specifications, industry codes and standards if applicable, and LANL supplied materials and deliverables. See Requesters Guide to Purchasing, Statement of Work for guidance on why and how to write a SOW.

4.7 Task Orders

Each task order must clearly define the work to be performed and the deliverables to be provided consistent with the SOW established in the task order agreement.

4.8 Establishment of Procurement QA Requirements

A successor step to identifying technical requirements is the identification of the necessary and sufficient quality requirements. At this point in the process, the TSME will identify only those quality requirements that are necessary to guarantee performance of the item or service consistent with the functional and performance/technical requirements.

For procured items, the TSME selects acceptance method(s) and specifies inspection requirements and acceptance criteria as appropriate.

With concurrence from the QSME, the TSME identifies those actions that are essential to ensure that the functional and technical requirements identified for procured ML-1 and ML-2 items or services are met. QA requirements may be applied to the procurement of ML-3 or ML-4 items/services at the discretion of the TSME and responsible Project Leader, Facility Manager, etc. The application of QA controls to the procurement of ML-3 and ML-4 items and services would typically occur for cost considerations; i.e., when the cost of an item or service is significant.

[1] **IF** the item/service to be procured is determined to be ML-1 and ML-2 and documented accordingly on a Purchase Request (Section 4.2.5), **THEN** the Requester completes Form 838c.

NOTE: Each Section of Form 838c must be completed and the printed name and signature of the TSME and QSME entered at the bottom of Page 2 of the form to indicate their approval.

[2] The selection of the quality clauses provided on Form 838c is based on the nature and intended end use of the item or service. Only clauses that are applicable should be invoked; e.g., if the service to be procured does not involve design activities, then "Design/Change Control" would not be selected.

NOTE: Completed 838c forms for ML-1 and ML-2 items and services must always indicate Quality Clause QC-21, “Subcontractor’s Facility (Visit)” and QC-22, “Subcontractor’s Facility (Resident)”.

[3] The requester must submit the completed Form 838c to the responsible SUP Procurement Specialist together with a copy of the Purchase Request.

[4] The responsible SUP Procurement Specialist must include the quality clauses indicated on the completed Form 838c in the purchase order/subcontract.

[5] With the exception of the items/commodities prone to be suspect/counterfeit that are listed in Section 4.4.4, and items/services required to be procured via the initiation of a purchase request also listed in Section 4.4.4, completion of Form 838c is not required for ML-3 or ML-4 items/services; however, the Requesting Organization has the option to apply QA requirements to ML-3 and ML-4 items and services.

4.9 Procurement Requirements for M&TE, Calibration Services or Standards

See Attachment 5 for guidance on establishing requirements for the procurement of calibration services or standards.

4.10 Solicitation Package Preparation and Issue

[1] Requesters and SUP will decide if a pre-proposal conference is required.

[2] SUP prepares solicitation packages to describe how the supplier is to address exceptions and clarifications and submits them to prospective offerors according to *Standard Practices and Policies*.

4.11 Bid/Proposal Evaluation

[1] The SUP Procurement Specialist reviews the responses to the solicitation packages and forwards supplier exceptions or clarifications to the requester for coordination with responsible TSME and QSME.

[2] TSME and QSME evaluate exceptions/clarifications.

The Requester conveys the results of the TSME/QSME evaluation to the SUP Procurement Specialist in writing.

[3] Prior to award, the requesting organization incorporates changes to procurement documents made in response to bid/proposal evaluations or contract negotiations. Approval of the revised documents is provided by the responsible TSME and QSME.

4.12 Qualification of Suppliers

[1] ML-1 and ML-2 items and services must be obtained from suppliers that have been evaluated in accordance with ISD 330-4.0, *Supplier Evaluations* and included on the IESL found on the PS-1 Home Page or similar list maintained by a LANL organization.

[2] The Quality Assessment Team of the PS-1 Group, maintains the IESL in a form that is accessible by LANL organizations.

The IESL contains the following information as a minimum:

[A] Supplier name and address
[B] Supplier phone number
[C] Quality Assurance Standard(s) used in the evaluation
[D] Applicable procurement requirement documents and revisions for which the supplier is qualified
[E] Commodities/services for which the supplier is qualified to provide to LANL
[F] Date due for re-qualification.

The PS-1 Quality Assessment Team (QAT) adds the supplier to the IESL upon qualification in accordance with the LANL Implementation Support Document, Supplier Evaluation.

[3] **IF** there is no supplier of the desired services (not items) on the IESL or no candidate supplier can meet the quality requirements specified in the procurement documents; **THEN** consider the actions listed below in the order presented as available options. The requesting organization, in conjunction with the QSME and TSME may:

[A] Identify additional acceptable suppliers.
[B] Re-evaluate the specified quality requirements.
[C] Define the factors associated with the supplier's inability to meet the specified quality requirements in sufficient detail to permit a Compensatory Action Plan (CAP) to be developed. See Attachment 6 "Compensatory Action Plan Requirements".

4.13 Commercial Grade Item Dedication

IF ML-1 and ML-2 items are requested for which no qualified suppliers are available, **THEN** the items may be procured via any SUP-controlled procurement method as commercial grade items and dedicated in accordance with ISD 330-10, *Commercial Grade Item Dedication*.

4.14 Purchase Order/Subcontract Changes

Changes to technical or quality requirements require review and approval by the same organizations that approved the original documents. The requester initiates contract modifications by submitting revised requirements documents to the SUP Procurement Specialist.

4.15 Disposition of Supplier Deviations

[1] Purchase orders for ML-1 and ML-2 items and services must require suppliers and sub-tier suppliers to identify to the responsible University Technical Representative (UTR) or requester (if no UTR has been assigned) any deviations from procurement document requirements, specifically to:

[A] Notify LANL when manufactured product or service does not meet established contract requirements; and to document the supplier's proposed disposition and technical (and where appropriate, Cost/Schedule) justification.

[B] Notify LANL when the supplier wants to propose changes to the contract documents unanticipated at time of award.

[2] Purchase orders for ML-1 and ML-2 items and services must require suppliers to provide supporting technical justification when requesting approval of "Use-as-is" or "Repair" dispositions from LANL when deviating from purchase order requirements. A "Scrap" disposition for nonconforming LANL-supplied materials also requires notification to the UTR (or requester if no UTR).

[3] The TSME dispositions and approves supplier-proposed/identified deviations. The TSME disposition is verified/checked by another TSME. The QSME concurs with disposition provided by the TSME. Printed names and signatures of the personnel performing these actions are entered on the resulting documentation.

[4] Documentation containing the results and approvals of the disposition evaluation are submitted to the responsible SUP Procurement Specialist for preparation of a Purchase Order Modification.

4.16 Supplier Submittals

Requesting organization ensures that all supplier documents that are required to be submitted by the purchase order are received.

4.17 Supplier Corrective Action

[1] The PS-1 QAT and other LANL organizations with similar responsibilities will establish and implement processes to gage and/or monitor the performance of ML-1 and ML-2 suppliers to ensure that their performance is acceptable.

[2] Requester organizations, including Site Support Services (SSS), will establish and maintain performance metrics to "grade" the performance of their suppliers of ML-1 and ML-2 items/services, and provide the results to PS-1 QAT (Mail Stop: P949; telephone: 665-5437); and to the responsible Procurement Specialist/UTR. The metrics may include information such as copies of NCRs, surveillance/audit findings, reports, data sheets, or other forms used to identify inadequate supplier performance.

[3] The Procurement Specialist/UTR and responsible QAT member will review the performance documentation when received to determine if immediate corrective actions are necessary. **IF** immediate is deemed necessary, **THEN** the actions delineated in 4.17.5 (below) will be followed.

[4] On a quarterly basis, the QAT reviews and evaluates the accumulated supplier performance results/ratings and immediately contacts the appropriate Procurement Specialist/UTR if substantive negative trends are apparent. **IF** the quarterly review indicates substantive negative trends, **THEN** the actions delineated in 4.17.5 (below) will be followed.

[5] Where warranted by negative performance results, the QAT in conjunction with the responsible Procurement Specialist/UTR initiates immediate communication and action with the supplier to obtain performance improvements. Requesters may request the QAT to initiate a request for supplier improvements when supplier nonconformances are significant.

[6] Supplier corrective actions requested by LANL should include a requirement for the supplier to identify the cause of the problem and the actions already completed or planned to be taken (including a schedule for implementation) to prevent recurrence of the identified conditions.

[7] The QAT evaluates the adequacy of the corrective actions. **IF** the corrective actions are acceptable, **THEN** the QAT closes the issue(s) after verifying that the corrective action has been implemented.

[8] Supplier nonconformances discovered by UTRs or other LANL personnel must be processed in accordance with the requirements of the applicable procedures for the control of nonconformances and corrective action.

5.0 TRAINING

5.1 Training

Training to this ISD is in accordance with LIR 300-00-04, *Laboratory Training: Essential Requirements*, utilizing a graded approach to the Systematic Approach to Training. Training will be developed in a phased approach as follows:

- Training Analysis
- Training Development
- Implementation and Evaluation

The following employees must receive training specific to this ISD within one year of the issue date of the ISD:

- QA Subject Matter Experts
- Responsible Line Managers
- Subject Matter Experts
- Procurement Specialists

Six months following the issue date of this procedure, all LANL receipt inspection personnel will be trained and certified by or for the PS-1 Procurement and Receipt Inspection Team. Training will be provided by the Issuing Authority (ADA).

5.2 Certification

Not applicable for this ISD.

6.0 RECORDS AND DOCUMENTS

6.1 Office of Record

PS-1 is the office of record for this ISD.

6.2 Documents

- Form 838c – Quality Assurance Supplement
- Purchase Request
- Receipt Inspection Documentation
- Compensatory Action Plan

6.3 Records Management

Records must be maintained in accordance with LIR 308-00-02, *Laboratory Records Management* .

Records generated as a result of this ISD are:

Record Identification	Record Type Determination	Protection/Storage Method	Processing Instructions
Form 838c – Quality Assurance Supplement	QA Record	Supervision MUST implement a reasonable level of protection to prevent loss and degradation	When the records are ready for final disposition, the records are transferred to Records Management in accordance with LIR 308-00-02, Laboratory Records Management.
Purchase Request	QA Record		
Receipt Inspection Documentation	QA Record		
Compensatory Action Plan	QA Record		

7.0 REFERENCES

10 CFR 830 Subpart A, *Quality Assurance Requirements*

DOE Order 414.1B, *Quality Assurance*

QC-1, *DOE/NNSA Weapon Quality Policy*

AP-341-502, *Management Level Determination for Structures, Systems, and Components*

AP-341-503, *Engineered Equivalent Determination*

ASME NQA-1-2000, *Quality Assurance Requirements for Nuclear Facility Applications*

LANL IP 300-SD, *Quality Assurance Program Document*

LANL Procurement Standard Practices 4.10, *Internal Reviews and Approval*

LANL Procurement Standard Practices 8.2, *Government Sources General*

LANL Procurement Standard Practices 8.4, *Orders with DOE M&O Contractors*

LANL Procurement Standard Practices 8.5, *Orders Against GSA Federal Supply Schedule*

LANL Procurement Standard Practices 42.5, *University Technical Representative*

LANL Procurement Standard Practices 44.1, *Intra-University Transactions*

LA-UR-98-2837 (Rev. 4, Feb. 2003), *Integrated Safety Managemen*t

LIR 230-01, *Graded Approach for Facility Work*

LIR 300-00-02, *Laboratory Records Management*

LIR 300-00-04, *Laboratory Training: Essential Requirements*

LIR 301-00-02, *Variances and Exceptions to Laboratory Operations Requirements*

LIR 308-00-04.1, *Procurement Quality*

LIR 308-00-05.0, *Software Quality Management*

LIR 402-10-3.2, *ES&H Management of Contractor Performed Facility Construction/Maintenance, Environmental Restoration/Decontamination and Decommissioning, and Related Drilling Operations*

OST220-03-01-CSM, *LANL Construction Specifications Manual*

OST220-03-01-ESM, *LANL Engineering Standards Manual*

ISD 311-1, *Manual for Preparing Policies, Procedures and Related Documents*

ISD 330-4, *Supplier Evaluation*

ISD 330-9, *Suspect/Counterfeit Items*

ISD 330-10, *Commercial Grade Item Dedication*

ISD 840-2, *Requester Guide for Meeting Requirements for Procurement of Items and Services*

8.0 ATTACHMENTS

8.1 Attachment 1: Specifying Performance and Technical Requirements

(Page 1 of 2)

Performance requirements: Consideration should be given to specifying requirements in performance terms to obtain the desired result. In identifying performance requirements, the Technical SME should consider the expertise and reliability of industry, and leaves the method or approach in developing the desired result to the judgment of the supplier. This type of description identifies "what" is required; i.e., the desired outcome, and avoids the "how" the item or service is achieved. The "how" represents the underlying process the supplier follows in achieving the result.

A performance requirement may simply be a description of the functional requirement coupled with a national code or standard which has to be met. Performance requirements can be used to describe individual items or total systems, or even entire projects. Performance specifying allows for full bidding competition based on non-restrictive requirements. As an example, the Technical SME may specify a pre-engineered steel structure and insulated metal wall and roofing system for a simple warehouse use. The performance requirement might identify the size of the enclosure (length x width x height), the color and style of wall and roof panels, the desired "U" value for heat transmission, size and location of doors and windows, and references to the applicable Building Code for wind and seismic design criteria and the Metal Building Manufacturers Association (MBMA) for fabrication and installation requirements.

Technical Requirements: Are described in accordance with salient features and critical characteristics. A variety of salient features (i.e. detailed attributes) can be used to describe an item or service. The selected salient features that comprise "necessary and sufficient technical requirements" are called the "critical characteristics." These constitute the basis for the identified requirements and acceptability criteria.

It is important that only the critical characteristics are identified in a procurement document and not a complete listing of features which may be associated with the item or service (copying all salient features of an item described in a catalog is unnecessary and may limit competition). In general, the identification of the critical characteristics relates to the "form, fit, and function" of the item or service.

The following are examples of salient features (from which critical characteristics can be selected for a specific item or service).

Product Identification: Color coding, display type (scale, graduations), enclosure type, markings, nameplate data, part number – unique identifier.

Physical Characteristics:

Capacitance
Cloud point
Costing
Color
Composite material hardness
Concentration
Conductivity
Continuity
Density/specific gravity
Dielectric strength
Dimensions
Drop point
Ductility
Durometer hardness
Elasticity
Fatigue resistance
Flammability
Flash point
General configuration or shape
Homogeneity
Inductance
Leachable halogen content
Luminescence
Material of construction
Resistance
Solubility
Spring constant
Oil/water separation
Permeability
Plating
Polarity
Pour point
Purity
Resilience
Surface finish
Surface hardness
Tensile strength
Torque
Viscosity
Weight

8.1 Attachment 1: Specifying Performance and Technical Requirements

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Features for Services: Personnel qualifications, regulatory controls, training requirements, and type of documentation.

Example of Identification of Functional, Performance, and Technical Requirements

Identification of Requirements for a Yellow Lab Coat:

The following illustrates the process for identifying functional performance, and technical requirements for a lab coat. The Technical SME first identifies those functions (functional requirements) which the lab coat must satisfy. The requirements can be described in either performance terms, which allows for maximum competition, or by critical characteristics. Either method chosen provides information suitable for use in the development of procurement documents.

Functional Requirement	Performance Requirements	Technical Requirements/Critical Characteristics
Prevent contamination of the user	Prevent contamination transfer	7.8-8.5 oz/yd, preshrunk, herringbone twill
	Openings for arms and neck sized to allow for unrestricted movement	Arm openings: 6 inch diameter; Neck opening: Size 17
	Bright, visible color	Federal Standard yellow 595a
	Durable fabric	100% cotton
	Easily removable	Hook and loop fasteners
Etc.	Etc.	Etc.

8.2 Attachment 2: Acceptance Criteria

(Page 1 of 3)

The Technical SME identifies in procurement specifications (Section 4.5), Statements of Work (Section 4.6), and/or Task Orders (Section 4.7), as applicable, criteria (acceptance methods) that will be used to determine that deliverables of suppliers of ML-1 and ML-2 items and services are acceptable. This may involve inspections, tests and test results, and review of documents. The acceptance methods specified demonstrate that ML-1 and ML-2 items and services will perform in accordance with functional requirements. For Commercial Grade Items, refer to Section 4.13.

Acceptance of Items

NOTE: With the exception of post-delivery/post-installation testing (see Attachment 2, page 3), ML-1 and ML-2 items may not be used for their specified/intended end use without receipt inspection documentation indicating satisfactory results.

Requesting organization specifies the acceptance methods and requisite documentation for ML-1 and ML-2 items in the Procurement Specification, SOW, Task Order, or other procurement documents, as applicable. Acceptance methods to be considered include:

- Source inspection/verification
- Receiving inspection
- Certificates of Conformance
- Post Installation/Post Delivery Testing

Source Inspections/Verifications

SUP forwards a copy of the purchase order and all authorized changes to the responsible LANL quality assurance organization before initiation of source verification activities.

Technical SME can specify in procurement documents that source verification be performed at the supplier's facility at intervals consistent with the complexity of the item considering:

- Criticality of dimensions,
- Critical nature of in-plant testing,
- Cost replacement,
- Supplier's history of performance, and
- Schedule requirements.

Only authorized and qualified Quality SME(s) may perform source verification.

Source verification activities (when required by procurement documents) include:

- Verifying that supplier submittals required by applicable procurement documents are approved by LANL and are in use,
- Witnessing of specified supplier activities and review of associated supplier documentation, including nonconformance reports,
- Documenting verification results,
- Notifying SUP and the requester of the results of the source verification,
- Furnishing source verification acceptance documentation to the supplier,
- Receipt inspection verifies receipt of source verification documentation from the supplier.

Receipt Inspection

Receipt Inspection is required for all ML-1 and ML-2 items. The responsible Technical SME develops an inspection plan to document the inspection attributes, methods, and acceptance criteria for procured ML-1 and ML-2 items. The inspection/acceptance criteria provide the receipt inspector the means to verify the salient features, critical characteristics, and documentation necessary to ensure the item ordered will perform satisfactorily in service. The Technical SME submits a copy of the inspection plan to the responsible receipt inspection organization.

8.2 Attachment 2: Acceptance Criteria

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The receiving inspection organization accepts ML-1 and ML-2 items in accordance with the inspection and acceptance criteria specified in the inspection plan. If the inspection plan is expired or unavailable, the inspector requests inspection and acceptance criteria from the requester. Receipt inspections may not be performed without available and current formal (written) inspection and acceptance criteria.

Minimum Receipt Inspection requirements include the following:

- Part number verification
- Quantity verification
- Identification and marking
- Physical damage and packaging
- Cleanliness
- Basic configuration
- Workmanship
- Suspect/counterfeit items

Note: Visual inspection is a subjective inspection intended to identify obvious abnormalities. This aspect of receiving inspection is used in conjunction with the verification of the inspection/acceptance criteria specified in the applicable inspection plan and is not used as the sole means of acceptance.

If inspections in addition to the basic attributes listed above are necessary, identify the additional inspection and acceptance criteria that you require. Additional attributes/requirements are documented in an Inspection Plan and may include but are not limited to the following:

- Verification of required supplier documentation (e.g., Certificate of Conformance, inspection and test reports, etc.)
- Dimensions (with tolerances)
- Critical/salient features (with tolerances)
- Other attributes

Receiving inspection organization performs a check to verify that the documentation received agrees with applicable procurement documents.

Receiving inspection organization examines incoming items for evidence of suspect/counterfeit parts as required by ISD 330-9, *Suspect/Counterfeit Items*.

Requesting organizations receive and accept ML-3 and ML-4 items; however, the PS-1 Receipt Inspection Team will perform the receipt inspection upon request.

Requester verifies that items have been accepted prior to the item's use or installation.

Organizations performing receiving inspections ensure that documentation resulting from receipt, source, and/or final inspection or testing for acceptance of items or services is maintained as QA records in accordance with LIR 300-00-02, *Laboratory Records Management*.

Copies of Nonconformance Reports (NCR) or other information concerning significant problems must be provided to the PS-1 Quality Assessment Team (QAT) at 665-4660 (FAX) or MS P949 (hard copy).

Twelve (12) months following the issue date of this procedure, all LANL receipt inspection personnel will be trained and certified by or for the PS-1 Procurement and Receipt Inspection Team (P&RIT).

Certificates of Conformance

Certificates of Conformance will be used for ML-1 and ML-2 items only. When a Certificate of Conformance is specified, the requesting organization includes the following requirements in the LANL procurement documents:

- The certification system, including the procedures for completing, reviewing, and approving the certificate is described in the supplier's quality assurance program.

8.2 Attachment 2: Acceptance Criteria

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- The certificate identifies the supplier's quality program by name and revision number, identifies the purchased item or service by name, and includes a unique identification number (that is, purchase order number, project number, part number).
- The certificate identifies the specific procurement requirements met by the purchased item. This is accomplished by including a list of the specific requirements or by providing a copy of the purchase order and the procurement specifications or drawings with the certificate. The procurement requirements identified include any approved changes, waivers, or deviations.
- The certificate identifies any procurement requirements not met, together with an explanation and the means to resolve the nonconformances.
- The person who is responsible for managing the quality assurance program and whose function is described in the supplier's quality assurance program signs or otherwise authenticates the certificate.

Requesting organizations may list Certificates of Conformance as a supplier provided document in applicable procurement documents.

Qualified LANL quality assurance auditors verify the validity of supplier certificates and the effectiveness of the certification system via audits. This verification is performed at intervals commensurate with the supplier's history of quality performance. Qualified LANL inspection/test personnel ensure that certificates of conformance meet applicable procurement document requirements.

Post Installation Testing/Post Delivery Testing

PIT/PDT is specified by a Technical SME in the Procurement Specification and includes test requirements and acceptance criteria.

PIT/PDT is conducted following receipt inspection at LANL and is used when it:

- Is difficult to verify the quality or technical characteristic of the item without it being installed or in use,
- Requires an integrated system checkout or test with other items to verify its quality/technical characteristics,
- Is not possible to demonstrate performance of its intended function except when installed or tested.

The Technical SME responsible for the PIT/PDT provides (formally notifies - in writing) the Receiving Inspection organization with the results of the PIT/PDT. The Receiving Inspection organization finalizes the receipt inspection based on the results; i.e., pass or fail, satisfactory or unsatisfactory. Thus the final receiving inspection acceptance process is completed by the Receiving Inspection organization upon acceptable completion and documentation of required PIT/PDT.

Acceptance of Subcontracted Services

When ML-1 and ML-2 subcontracted services are procured, the services are accepted by the requesting organization using one or more of the following methods as defined in the applicable procurement document:

- Technical verification of data produced using methods specified in appropriate LANL procedures.
- Surveillance/audit of the activity.
- Review of objective evidence (e.g., certifications, technical reports, inspection reports, etc.) for conformance with procurement document requirements.

Deficiencies identified during the acceptance of services are processed by the responsible Technical SME in accordance with Section 4.14 and provides a copy of the deficiencies to the responsible SUP Procurement Specialist who, in turn, notifies the supplier.

For subcontracted inspections, an inspector certified to the requirements of ASME/NQA-1 or an equivalent national standard is utilized when the inspection contains designated LANL hold points or witness points, or the inspector rejects or accepts the item based on LANL established written acceptance criteria. The type and level of certification is consistent with the inspection requirements and acceptance criteria.

Refer to the Requesters Guide for Meeting Requirements for Procurement of Items & Services for guidance on selecting item acceptance methods and specifying detailed item inspection requirements and acceptance criteria.

8.3 Attachment 3: Packaging, Handling, Shipping, and Storage (PHSS)

A. General

[1] Organizations requesting off-site-procured (for example, stores stock requests, purchase requests, spare parts data sheets) or on-site-manufactured items are responsible for verifying that storage space of the specified level is available for the item prior to its receipt.

[2] PHSS (including shelf-life and in-storage maintenance activities) will be conducted in accordance with the requirements specified in this ISD and other documents (e.g., procedures, drawings, specifications, procurement documents, supplier document submittals) that prescribe and provide a means of controlling these activities.

[3] Hazardous materials are packaged, labeled, stored, and shipped in accordance with applicable Department of Energy (DOE) and Department of Transportation (DOT) regulations. For additional information, contact the facility/area Hazardous Materials Transportation Representative.

[4] Qualifications of personnel operating and maintaining special handling and lifting equipment will be established by each organization having the responsibility for PHSS of items. Operators of special handling and lifting equipment shall be experienced or trained in the use of the equipment.

[5] Tools and equipment used in special PHSS activities that require periodic inspection, testing, and maintenance shall be identified. Inspection, test, and maintenance of special handling tools and equipment shall be performed and documented in accordance with approved organizational procedures at specified intervals.

B. Item Classification

[1] Requirements are divided into four classification levels (A, B, C, and D). The level assigned to each requirement will address specific protective measures necessary to prevent damage or deterioration of items, or contamination to or by an item. These requirements are based upon the important physical characteristics of the item with respect to safety, reliability, and operation. Within the scope of each level may be a range of controls and the detailed requirements may vary item by item depending on the specified importance (such as safety or reliability) of the item to its end use.

[2] The manufacturer's documented standard or minimum/maximum requirements for items are to be used when assigning classification levels.

[3] Technical SMEs assign item classification levels in accordance with the basic guidance provided in this attachment. Items should be classified at a level that provides all the needed protective controls. If not possible or practical due to size, quantity, etc. or if the controls needed are not identified within this procedure, the item shall be classified at the lowest level possible and additional controls specified in accordance with Section C, "Specifying PHSS Requirements" (below).

[4] Item Classification Levels (A, B, C, and D)

a. **Level A** includes those items/materials that are exceptionally sensitive to environmental conditions and require special measures for protection from one or more of the following:
   - Temperatures outside required limits,
   - Sudden temperature changes,
   - Humidity,
   - Vapors,
   - Accelerating forces,
   - Physical damage,
   - Airborne contamination (for example, rain, snow, dust, dirt, salt spray, and fumes),
   - Hazardous material.

   Examples of items/material typically included in this classification level are:
   - Special electronic equipment and instrumentation,
   - Special materials such as chemicals that are sensitive to the environment,
   - Special Nuclear Material.

8.3 Attachment 3: PHSS

b. **Level B** includes those items/material that are sensitive to environmental conditions but do not require special protection as required for Level A items/materials. Level B items/materials require protection from one or more of the following:
- The effects of temperature extremes and humidity (to prevent condensation),
- Vapors,
- Accelerating forces,
- Physical damages,
- Airborne contamination (for example, rain, snow, dust buildup, dirt, salt spray, and fumes).

Examples of items/material typically included in this classification are:
- Instrumentation,
- Electrical penetrations,
- Batteries,
- Welding electrodes and wire (welding electrodes, hermetically sealed in metal containers, may be stored under conditions for Level C items/material),
- Control rod drives,
- Motor control centers, switchgear, and control panels,
- Motors and generators,
- Precision machined parts,
- Gaskets, o-rings,
- Air-handling filters,
- Chemicals sensitive to environmental influences.

c. **Level C** includes those items/materials that protection from water vapor and condensation is not as important as for Level B items/materials, but which require protection from one or more of the following:
- Exposure to the environment,
- Airborne contamination (for example, rain, snow, dirt, and salt spray),
- Accelerating forces,
- Physical damage.

Examples of items/material typically included in this classification are:
- Pumps,
- Valves,
- Fluid filters,
- Compressors,
- Instrument cable,
- Thermal insulation,
- Fans and blowers,
- Cement,
- Process chemicals not sensitive to environmental influence.

d. **Level D** includes items/materials that are less sensitive to the environment than those in Level C. In accordance with paragraphs B.1 and B.3 above, these items may require additional protection against the weather, acceleration forces, airborne contamination or physical damage when specified by the Technical SME. If additional protection is required, then the item should be considered for reclassification to at least Level C.

Examples of items/material typically included in this classification are:
- Tanks
- Heat exchangers and parts
- Accumulators
- Demineralizers
- Evaporators
- Piping
- Electrical cable (jacketed)
- Structural items

8.3 Attachment 3: PHSS

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- Reinforcing steel
- Aggregates
- Expendable support items/material

[5] Unless changed and documented by the originating or using organization:

- Items are to be processed to the requirements of the appropriate storage level. However, items may be stored either at that level or at a higher level, e.g., an item classified level C could be packaged as level C and then stored as either level C or B.

- Any package unit or assembly made up of items or different levels may be classified and processed to the lowest level appropriate for the overall unit/assembly, but will include additional controls specified for component items in accordance with Section C, as deemed appropriate, to maintain quality of all respective items and the overall unit/assembly.

- A level shall be indicated for each part of a disassembled unit.

C. Specifying PHSS Requirements

[1] Technical SMEs (TSMEs) are to specify PHSS requirements for items as well as any special requirements associated with the items. TSMEs are to designate item classification levels per Section B and, when applicable, any protective controls that are in addition to those established within the assigned classification level.

[2] The supplier standards will be considered for use when establishing packaging and shipping requirements. If supplier standards are inadequate to provide needed protective controls, then additional controls are to be provided.

[3] Special PHSS requirements are applied to items/material based on their sensitivity to environmental conditions, resistance to physical forces, relative replace ability, and importance to their end use. The following PHSS elements will be considered by the Technical SME:

- Blocking, bracing, chocking, strapping, and orientation
- Cleaning,
- Containment and confinement,
- Desiccants,
- Environmental protection (for example, dust, dirt, water, sunlight, salt spray),
- In-storage inspection, maintenance, and testing,
- Lifting points and methods,
- Packaging,
- Preservation,
- Recording devices (for example, temperature, pressure, humidity, and loading),
- Sealings and coatings,
- Transportation methods.

[4] Requesters identify in procurement documents the requirements (as determined by the Technical SME) including any special requirements providing added protective controls for packaging, handling, shipping, storage, shelf-life, and in-storage maintenance activities. Requesters of on-site-manufactured items will also identify these requirements in the appropriate documents. Procurement and on-site manufacture documents will clearly identify the storage level to be applied to items upon their receipt/manufacture.

[5] When required for critical, sensitive, perishable, or high-value items, specific procedures for handling, storage, packaging, shipping, and preservation will be used.

[6] When required, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) will be specified and provided and their existence verified.

8.4 Attachment 4: Marking and Identification Guidance

The responsible Technical SME should consider the following as possible requirements for marking and identification:

- The English language is to be used. Duplicate marking may be made in other languages.
- References to weights are to be in pound units. Duplicate markings in other systems may also be indicated.
- Container markings are to appear on a minimum of two sides of a container, preferably on one side and one end.
- When metal stamps are employed for identification, they shall be low stress, rounded bottom type.
- When vibrating marking tools are used, they are to be fitted with a carbide marking tip or its equivalent, and are to be designed to provide a rounded impression not to exceed 0.010 in. (0.25 mm) in depth. Etching is not to be used on nickel alloys, on weld areas, or sensitized areas of stainless steel. Electric-arc marking pencils are not to be used.
- When container information relative to handling and special instructions is required, such information is to be preceded by the word 'CAUTION' in letters that are at least 1/2 inch (12.7 mm), as permitted by container size.
- Container markings are to include the following information:
  - Destination
  - Return address
  - Package numbers showing the purchase or order number, followed by the package number and the total number of packages
  - Material identification number
  - Handling instructions (e.g., Fragile, Center of Gravity, Keep Dry, Keep Refrigerated, This Side Up, Sling Here, Do Not Freeze) and stacking limitations, as appropriate
  - Weight of package (in excess of 100 lb. [45.5 kg])
  - Special instructions (Desiccant Inside, Special Inspection, Storage, Unpacking Restrictions, etc.) as appropriate
  - Marking of items not within a container, such as pipe, tanks, and heat exchangers, are to exhibit specified information in a location which is in plain unobstructed view, but not directly applied to bar austenitic stainless steel or nickel alloy metal surfaces of the item.
  - Storage level if specified in the requirement document

Examples of marking:

- Supplier name
- Equipment name
- LANL unique identification number
- Model number
- Serial number
- Heat/lot/batch number
- Purchase order number(s)
- Project number
- Design date
- Volume, test pressure, set points, voltage, amperage, etc.

8.5 Attachment 5: Guidance for Procurement of M&TE, Calibration Services or Standards

1. When preparing procurement documents for measuring and test equipment (M&TE), calibration services or standards, the requester should consider requiring the supplier to provide documentation of traceability to one or more of the following:

    - National Institute of Standards and Technology (NIST) or the U.S. Naval Observatory,
    - Fundamental or natural physical constants with values assigned or accepted by NIST,
    - National measurement standards of other countries which are correlated with the U.S. national standards, as approved by NIST,
    - Defined and documented consensus measurement standards,
    - Defined and documented bases for calibration when no nationally recognized standards exist.

2. When preparing procurement documents for M&TE, calibration services or standards, the requester should consider requiring the supplier to provide documentation that includes the following information:

    - Unique identification,
    - Description/name,
    - Manufacturer and model number,
    - Date calibration was performed,
    - Unique identification of M&TE or standard(s) used,
    - Actual readings if applicable,
    - Indication that the calibration was performed under a program meeting a recognized national standard for calibration.

3. Additional requirements may be specified in the procurement document based on the end use, including, but not limited to:

    - Uncertainty of M&TE or standard(s) used to calibrate the calibration instrumentation,
    - Environmental conditions (for example, temperature) during calibration.

4. First-time procurement of new M&TE may be coordinated with the LANL Standards and Calibration Laboratory (MSM-3) so that they are aware of the M&TE needed to calibrate the new M&TE.

5. Procurement of M&TE or calibration services for a weapons program (other than direct replacement) is coordinated with the LANL Standards and Calibration Laboratory by obtaining the Standards Laboratory Manager or metrology engineer's approval of the purchase request.

8.6 Attachment 6: Compensatory Action Plan Requirements

1. The Corrective Action Plan (CAP) is a LANL document designed to compensate when a supplier of services is unable to meet specified quality requirements.

2. The CAP process includes the following, as a minimum:

   - The requesting organization reviews the supplier's quality program to determine the quality requirements the supplier cannot meet.
   - The requesting organization prepares a CAP that provides compensatory actions for each of the supplier's QA Program weaknesses. The CAP can include supplier actions as well as LANL actions.

   The following are examples of actions that can be included in the CAP:

   - LANL surveillances of supplier activities,
   - LANL review of supplier generated documents such as procedures and drawings,
   - Supplemental quality audits,
   - Performance of specific LANL receipt inspections,
   - Supplier changes to the supplier's process controls,
   - The requesting organization identifies the LANL personnel/organization expected to implement the CAP and qualified to perform the various actions required by the CAP. This information is included in the CAP, if appropriate.
   - The requesting organization, the Technical SME and the Quality SME review and approve the CAP as part of the procurement document review process.
   - The SUP Procurement Specialist incorporates the CAP, including the LANL and supplier compensatory actions, into the purchase order.

3. The LANL requesting organization, in coordination with the supplier, schedules and tracks the compensatory actions to completion.

8.7 Attachment 7: ISD 840.1 Implementation Schedule

Laboratory-Wide Milestone	Schedule
1. Issue ISD-824-1.0	1st Quarter FY06
2. Computer-based training modules available.	2nd Quarter FY06
3. Existing procurement procedures to be reviewed for compliance to ISD-824-1.0	2nd Quarter FY06
4. Implementing procurement procedures to be revised to comply with ISD-824-1 and issued.	3rd Quarter FY06
5. Training to be developed for implementing procurement procedures, as necessary. Note: ISD-824-1.0 training may be adequate.	3rd Quarter FY06
6. Training (ISD & implementation level procedure, as necessary) completed for all identified (see RDL milestone below) requesters, Technical SMEs, Quality SMEs, procurement specialists, UTRs, and line managers.	4th Quarter FY06
7. Completion of training/certification for LANL Receipt Inspectors.	1st Quarter FY07
8. RDLs to provide list of all trained requesters, Technical SMEs, Quality SMEs, procurement specialists, UTRs, and line managers authorized to implement the requirements of ISD-824-1.0.	1st Quarter FY07
9. Full compliance to ISD-824-1.0 and implementing procedures.	1st Quarter FY07